

**REMARKS****Status of the Claims**

Claims 1-20 are pending. Claims 1-10 and 15-20 are withdrawn from consideration and are canceled herein. Claims 11-14 are allowed.

**Claim amendments**

Claims 1-10 and 15-20 are canceled as non-elected claims.

**Objection To Specification**

The previous Examiner in the Office Actions mailed 06/03/03 and 01/14/03 stated that the structure and physical activities of the proteins Smad6 and Hoxc-8 are essential to practice the claimed invention and that this information is disclosed in some of the non-patent publications incorporated by reference in the specification. This Examiner stated that, as essential material, incorporation by reference is improper. Applicant respectfully disagrees that the structure, i.e., the sequence and physical activities of Smad6 and Hoxc-8 are essential to the practice of the invention.

Applicant submits that the practice of the present invention does not require knowledge about the structural features of Smad6 and Hoxc-8. The essential feature of the present invention is being able to produce and utilize a Smad6/Hoxc-8 protein complex. Thus, the present invention only requires cloning and expressing Smad6 and Hoxc-8, individually or as a fusion protein, in

suitable vectors. Smad6 and Hoxc-8 are well known in the art and genomic sequences and protein sequences are identified in Genbank. One of ordinary skill in the art can readily identify and obtain the genomic sequences for these proteins and clone these proteins according to standard genetic engineering procedures. The plasmids used in the practice of this invention to clone these proteins are commercially available from Clontech and Invitrogen and the instant specification more than adequately teaches how to construct vectors that express Smad6 and Hoxc-8 proteins individually or as a fusion protein.

Furthermore, Applicants submit that, although not required to practice the instant invention, should one of ordinary skill in the art wish to sequence and characterize the expression products of the vectors, Smad6 and Hoxc-8 proteins are well known in the art and have been extensively studied. One of ordinary skill in the art would readily recognize that the expression product of the vectors was indeed Smad6 and/or Hoxc-8 proteins based on description and sequences readily available. Hence, Applicant submits that the Smad6 and Hoxc-8 proteins have been adequately described in the present application.

Although the Board of Patent Appeals and Interferences did not address the issue of improper incorporation of essential material in its September 29, 2004 Decision reversing the rejection of claims 11-14 as lacking a written description to reasonably convey that Applicants had possession of the claimed invention, the Board of Patent Appeals and Interferences concurred with Applicants arguments that Smad6 and Hoxc-8 are well-known in the art. The

Board of Patent Appeals and Interferences stated that it is well settled that "a patent specification need not detail and preferably omits, what is known or understood in the art" (pg. 3, 2<sup>nd</sup> PP). Therefore, Applicants have provided sufficient written description to enable the invention.


The MPEP at 608.01(p) defines essential material as that which is necessary to either (1) describe the claimed invention, **(2) provide an enabling disclosure** (Applicants' emphasis) or (3) describe the best mode of the claimed invention. As per the Decision of the Board of Patent Appeals and Interferences, Applicants have provided an enabling disclosure which discloses all essential and adequate material to practice the instant invention. Therefore, even should any of the non-patent publications disclose sequences for Smad6 and/or Hoxc-8, this cannot be deemed essential material, but rather a state of the art disclosure of what is known and available. Therefore, the incorporation of these non-patent publications by reference is not improper. Accordingly, Applicants respectfully request that the objection to specification be withdrawn.

This is intended to be a complete response to the Office Action mailed October 27, 2004. Applicants respectfully request that claims 11-14 proceed to allowance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Applicants attach a Petition for a Two Month Extension of Time. Please credit the \$225 petition fee to the credit card identified on the

attached Form PTO-2038. Please debit any insufficiency in the fees from Deposit Account No. 07-1185 upon which the undersigned is allowed to draw.

Respectfully submitted,

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